UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/266,803	03/12/1999	GREGORY M. GLENN	PM-256865	6258

7590 09/27/2004

Erich E Veitenheimer
Morgan Lewis & Bockius
1111 Pennsylvania Avenue NW
Washington, DC 20004

EXAMINER	
EWOLDT, GERALD R	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 09/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/266,803	GLENN ET AL.	
	Examiner	Art Unit	
	G. R. Ewoldt, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *112,115-126 and 129-134* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *112,115-126 and 129-134* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination (RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's amendments and remarks filed 7/15/04 have been entered.

2. Claims 112, 115-126, and 129-134 are pending and under examination.

3. In view of Applicant's amendment and remarks only the following rejections remain.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 123 stands rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

As set forth previously, the specification and the claims as originally filed do not provide support for the invention as now claimed, specifically, the "formulation comprises an ADP-ribosylating exotoxin B subunit".

Applicant's arguments, filed 7/15/04, have been fully considered but they are not persuasive. Applicant argues that support for the limitation can be found at pages 16-17.

A review of the specification shows that adjuvants comprising the B subunit of cholera toxin (CT) are disclosed at page 15 of the specification and in original Claim 23. Applicant has provided no evidence, however, that adjuvants comprising B subunits of other bAREs were described in the specification or

claims as filed. Applicant has merely argued that other bAREs are structurally related to CT. This argument does not overcome the fact that these other bARE B subunits are not disclosed in the specification as adjuvants encompassed by the method of the claims.

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 112, 115-126, and 129-134 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claim 32 of copending Application No. 10/633,626. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims encompass a method comprising inducing an immune response comprising applying a formulation comprising an antigen and an adjuvant to hydrated skin.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8. Claims 112, 115-126, and 129-134 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 32 and 33 of copending Application No. 10/701,069. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims encompass a method comprising inducing an immune response

comprising applying a formulation comprising an antigen and an adjuvant to hydrated skin.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9. Claims 112, 115-126, and 129-134 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 71-72, 75-87, and 90-97 of copending Application No. 09/337,746. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims encompass a method comprising inducing an immune response comprising applying a formulation comprising an antigen and an adjuvant to skin.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant has traversed the obviousness-type double patenting rejections of Sections 7-9 above but provided no explanations. Accordingly, Applicant's position on the merits of the rejections is unclear. Regardless, as indicated by Applicant, upon the finding of allowable claims, provisional obviousness-type double patenting rejections will be withdrawn.

10. The following are new grounds for rejection.

11. Claims 112, 115-126, and 129-134 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for,

a method for inducing an immune response (TCI) comprising applying a formulation to hydrated skin,

does not reasonably provide enablement for,

a method for dry TCI, i.e., a method wherein no hydration of the skin has been performed and wherein a dry formulation is employed.

As set forth previously (in the action mailed 10/15/02), the success of the instant method must be considered unexpected and thus highly unpredictable:

> "Paul and Cvec (1995) stated that it is "impossible to immunize epicutaneously with simple peptide or protein

> solutions." Thus, transcutaneous immunization as described herein would not be expected to occur according to this group,"

Thus, the specification must disclose some specific demonstration of enablement commensurate with the scope of the claims. Mere assertions that the method works cannot be considered to be enabling.

In the instant case, every example disclosed in the specification comprises either prehydrated skin or skin on which the "dry" formulation is dissolved in solution and placed on the skin (effectively hydrating the skin at the time of TCI). Accordingly, the specification discloses no instances in which a dry formulation is administered to dry skin. Thus, it is again the Examiner's position that hydrating or wetting of the skin comprises an essential element that must be recited in the claims.

In re Wands, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. Thus, in view of the quantity of experimentation necessary, the lack of sufficient working examples encompassing the scope of the claimed method, the unpredictability of the art, and the lack of sufficient guidance in the specification, it would take undue trials and errors to practice the claimed invention.

12. Claims 112, 115-126, and 129-134 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claim 32 of copending Application No. 10/633,626. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims encompass a method comprising inducing an immune response comprising applying a formulation comprising an antigen and an adjuvant to hydrated skin.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

13. No claim is allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald

Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

15. **Please Note**: Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

G.R. Ewoldt, Ph.D.
Primary Examiner
Technology Center 1600

9/23/04
G.R. EWOLDT, PH.D.
PRIMARY EXAMINER